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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group: 3738  
Customer No.: 23643  
Confirmation No.: 9094  
Application No.: 10/044,031  
Invention: **Purified Submucosa Graft Material**  
Applicant: Stephen F. Badylak et al.  
Filed: January 11, 2002  
Attorney  
Docket: 3220-69262  
Examiner: Paul B. Prebilic

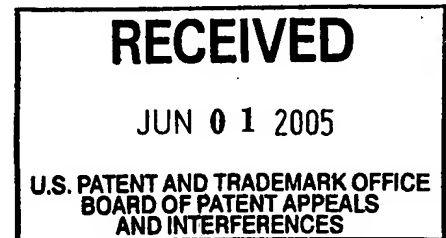
### Certificate Under 37 CFR 1.8(a)

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Rebecca Ball  
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### SUPPLEMENTAL RESPONSE UNDER 37 C.F.R. § 1.607(a)(5)

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Sir:

In response to the Office Action mailed on February 24, 2005 in the above-captioned application, Applicants file this response in an attempt to further comply with 37 C.F.R. § 1.607(a)(5). Applicants filed a response on March 25, 2005 to comply with 37 C.F.R. § 1.607(a)(5). Applicants believe that no fees are required with this response. If any fees are required, the Commissioner is hereby authorized to charge any such fees or credit any overpayment to our Deposit Account No. 10-0435, with reference to our Matter No. 3220-69262.

**Compliance with 37 C.F.R. § 1.607(a)(5)**

The present claims are provided with the number of an exemplary drawing element, if applicable, in parenthesis which supports the immediately preceding claim limitation. A reference to an exemplary corresponding page and line number(s) or paragraph and line number(s) or column and line number(s) of the specification which supports the immediately preceding claim limitation is also provided in brackets.

**Claims 1-20 (support in U.S. Appl. Serial No. 60/024,693)-**

1. (Original) A graft prosthesis [page 1, lines 2-6], comprising:  
a purified, collagen-based matrix structure removed from a submucosa tissue source [page 4, lines 11-25], said purified structure having a contaminant level making said purified structure biocompatible [page 4, lines 15-19], said purified structure further having an endotoxin level of less than 12 endotoxin units per gram [page 4, lines 15-19; page 10, line 32 through page 11, line 2].
2. (Original) The graft prosthesis of claim 1, wherein said endotoxin level is less than 10 endotoxin units per gram [page 4, lines 15-19; page 10, line 32 through page 11, line 2].
3. (Original) The graft prosthesis of claim 2, wherein said endotoxin level is less than 5 endotoxin units per gram [page 4, lines 15-19; page 10, line 32 through page 11, line 2].
4. (Original) The graft prosthesis of claim 1, wherein said purified structure has a bioburden level of less than 2 colony forming units per gram [page 4, lines 15-19; page 9, lines 33-34; page 10, line 32 through page 11, line 2].
5. (Original) The graft prosthesis of claim 4, wherein said bioburden level is less than 1 colony forming unit per gram [page 4, lines 15-19; page 9, lines 33-34; page 10, line 32 through page 11, line 2].

6. (Original) The graft prosthesis of claim 5, wherein said bioburden level is less than 0.5 colony forming units per gram [page 4, lines 15-19; page 9, lines 33-34; page 10, line 32 through page 11, line 2].

7. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source [page 4, line 27].

8. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and delaminated submucosa tissue source [page 8, lines 2-6; page 4, line 33 through page 5, line 14].

9. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source pretreated with an oxidizing agent to remove at least a portion of the source of endotoxin [page 9, lines 1-2].

10. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and then delaminated submucosa tissue source [page 8, lines 2-6; page 4, line 33 through page 5, line 14].

11. (Original) A graft prosthesis [page 1, lines 2-6] comprising:  
a purified, collagen-based matrix structure removed from a submucosa tissue source [page 4, lines 11-25], said purified structure having an endotoxin level of less than 12 endotoxin units per gram [page 4, lines 15-19; page 10, line 32 through page 11, line 2].

12. (Original) The graft prosthesis of claim 1, wherein said purified structure is tubular [page 10, line 25 through page 11, line 18].

13. (Original) The graft prosthesis of claim 1, wherein said purified structure is adapted for tendon or ligament repair [page 2, line 19].

14. (Original) The graft prosthesis of claim 1, comprising multiple layers, wherein each of said layers is formed of said collagen-based matrix [page 9, lines 8-24; page 4, lines 19-25].

15. (Original) The graft prosthesis of claim 1, wherein said purified structure is comprised of tela submucosa in strip form, said graft prosthesis comprising a plurality of said tela submucosa strips fused to one another.

16. (Original) A graft prosthesis [page 1, lines 2-6], comprising:  
a purified collagen-containing matrix obtained from a mammalian tissue source [page 4, lines 26-29], said matrix comprising tela submucosa [page 4, line 13] and residual contaminants from said mammalian tissue source [page 5, lines 22-25], said matrix obtainable by a process which comprises treating said mammalian tissue to remove at least a portion of endotoxin contaminants [page 4, lines 15-19; page 10, lines 26-29] and then removing said matrix from the treated mammalian tissue [page 10, lines 29-32], and disinfecting said matrix so that it has an endotoxin level of less than 12 endotoxin units per gram [page 4, lines 15-19; page 10, line 29 through page 11, line 2].

17. (Original) The graft prosthesis of claim 16, wherein said matrix has a contaminant level making said matrix biocompatible in humans [page 4, lines 6-33].

18. (Original) The graft prosthesis of claim 16, wherein said disinfecting comprises contacting said mammalian tissue with an oxidizing agent [page 9, lines 1-2].

19. (Original) The graft prosthesis of claim 17, wherein said mammalian tissue source is a porcine tissue source [page 7, lines 4-7].

20. (Original) The graft prosthesis of claim 19, wherein said porcine tissue source is porcine small intestine [page 7, lines 4-7].

**Claims 1-20 (support in U.S. Appl. Serial No. 60/024,542)-**

1. (Original) A graft prosthesis [page 3, lines 12-16], comprising:  
a purified, collagen-based matrix structure removed from a submucosa tissue source [page 3, lines 13-14; page 6, lines 12-18], said purified structure having a contaminant level making said purified structure biocompatible [page 3, lines 16-20], said

purified structure further having an endotoxin level of less than 12 endotoxin units per gram [page 4, lines 8-12; page 7, lines 16-17].

2. (Original) The graft prosthesis of claim 1, wherein said endotoxin level is less than 10 endotoxin units per gram [page 4, lines 8-12; page 7, lines 16-17].

3. (Original) The graft prosthesis of claim 2, wherein said endotoxin level is less than 5 endotoxin units per gram [page 4, lines 8-12; page 7, lines 16-17].

4. (Original) The graft prosthesis of claim 1, wherein said purified structure has a bioburden level of less than 2 colony forming units per gram [page 4, lines 8-12; page 7, lines 16-17].

5. (Original) The graft prosthesis of claim 4, wherein said bioburden level is less than 1 colony forming unit per gram [page 4, lines 8-12].

6. (Original) The graft prosthesis of claim 5, wherein said bioburden level is less than 0.5 colony forming units per gram [page 4, lines 8-12].

7. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source [page 5, lines 16-17].

8. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and delaminated submucosa tissue source [page 5, lines 16-17; page 6, lines 12-32].

9. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a delaminated submucosa tissue source pretreated with an oxidizing agent to remove at least a portion of the source of endotoxin.

10. (Original) The graft prosthesis of claim 1, wherein said purified structure comprises a cleaned and then delaminated submucosa tissue source.

11. (Original) A graft prosthesis [page 3, lines 12-16] comprising:  
a purified, collagen-based matrix structure removed from a submucosa tissue source [page 3, lines 13-14; page 6, lines 12-18], said purified structure having an endotoxin level of less than 12 endotoxin units per gram [page 4, lines 8-12; page 7, lines 16-17].

12. (Original) The graft prosthesis of claim 1, wherein said purified structure is tubular [page 9, lines 21-35].

13. (Original) The graft prosthesis of claim 1, wherein said purified structure is adapted for tendon or ligament repair [page 2, lines 7-11].

14. (Original) The graft prosthesis of claim 1, comprising multiple layers, wherein each of said layers is formed of said collagen-based matrix [page 5, lines 7-10].

15. (Original) The graft prosthesis of claim 1, wherein said purified structure is comprised of tela submucosa in strip form, said graft prosthesis comprising a plurality of said tela submucosa strips fused to one another.

16. (Original) A graft prosthesis [page 3, lines 12-16], comprising:  
a purified collagen-containing matrix obtained from a mammalian tissue source [page 3, lines 13-14 and 21-24; page 6, lines 12-18], said matrix comprising tela submucosa [page 3, lines 13-14 and 21-24; page 6, lines 12-18;] and residual contaminants from said mammalian tissue source [page 2, line 32 through page 3, line 1], said matrix obtainable by a process which comprises treating said mammalian tissue to remove at least a portion of endotoxin contaminants [page 5, lines 2-31] and then removing said matrix from the treated mammalian tissue [page 5, lines 2-31], and disinfecting said matrix so that it has an endotoxin level of less than 12 endotoxin units per gram [page 5, lines 24-31; page 7, lines 16-17].

17. (Original) The graft prosthesis of claim 16, wherein said matrix has a contaminant level making said matrix biocompatible in humans [page 5, lines 24-31; page 7, lines 7-23].

18. (Original) The graft prosthesis of claim 16, wherein said disinfecting comprises contacting said mammalian tissue with an oxidizing agent [page 6, lines 27-29; page 8, lines 23-25].

19. (Original) The graft prosthesis of claim 17, wherein said mammalian tissue source is a porcine tissue source [page 5, lines 10-13].

20. (Original) The graft prosthesis of claim 19, wherein said porcine tissue source is porcine small intestine [page 5, lines 10-13].

## CONCLUSION

Applicants have complied with 37 C.F.R. § 1.607(a)(5) for application serial number 60/024,693 and 60/024,542. Additionally, Applicants have completed compliance for application serial number 10/044,031 and for priority application serial numbers 09/798,441 and 08/916,490.

Respectfully submitted,

A handwritten signature in black ink that reads "Rebecca Ball". The signature is written in a cursive style with a large, stylized "R" and "B".

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